

### EXAMINER'S AMENDMENT

1. An Examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.
2. Authorization of this Examiner's amendment was given in a telephone interview with Mr. Daniel Pereira on January 4, 2011 and January 6, 2011.
3. The Claims have been amended as follows:

Claim 2 (Currently Amended) [[:]] A method for reducing the effect of a fructosyl lysine compound in an assay of a glycated protein-containing sample, the method comprising treating the sample with a protease to release free fructosyl valine or fructosyl valylhistidine,

reacting a fructosyl peptide oxidase with the released fructosyl valine or fructosyl valylhistidine in the sample at a pH of 4.0 to 7.0 to produce hydrogen peroxide thereby reducing the effect of fructosyl lysine compound in the assay,

measuring the ~~product of the reacting~~ hydrogen peroxide at a pH of 4.0 to 7.0; and

correlating the measuring of the ~~product~~ hydrogen peroxide to the presence or level of glycated protein in the sample.

Claim 3 (Currently Amended)[[:]] A method according to claim 2, wherein the glycated protein is a glycated hemoglobin.

Claim 4 (Currently Amended) [[:]] ~~A~~ The method according to of claims claim 2 or 3,  
wherein the protease is obtained from:

(a) a microorganism belonging to ~~the~~ a genus selected from the group consisting of  
Bacillus, Aspergillus, ~~or~~ and Streptomyces, or

(b) ~~is obtained from~~ a gene of the microorganism of (a) through a gene recombination  
technology.

Claim 7 (Currently Amended) [[: ]] ~~A~~ The method according to of claim 2, wherein the  
enzyme for assaying fructosyl valine or fructosyl valylhistidine is a fructosyl peptide oxidase.

Claim 8 (Cancelled)

Claim 9 (Currently Amended) [[: ]] A reagent for assaying glyated protein with reduced  
effect of a fructosyl lysine compound, which comprises : [[at least]]

(A) a protease [[:]] ;

(B) an oxidase which specifically acts on fructosyl valine or fructosyl valylhistidine at a  
pH of 4.0 to 7.0 to thereby produce hydrogen peroxide[[:]] ; and

(C) a reagent for measuring hydrogen peroxide.

Claim 10 (Currently Amended) [[: ]] A method for reducing the effect of a fructosyl lysine  
compound in an assay of fructosyl valine or fructosyl valylhistidine in a sample, the method  
comprising:

[[causing]] reacting at least one of the following (A) to (C) with [[at least the following  
(A) to (C) to act on]] free fructosyl valine or fructosyl valylhistidine at a pH of 4.0 to 7.0

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after the sample has been reacted with a protease to release free fructosyl valine or fructosyl valylhistidine; and recovering a product resulting from the action of (A) to (C) in the presence or absence of fructosyl valine or fructosyl valylhistidine in the sample[: ]

- (A) a fructosyl peptide oxidase,
- (B) a reagent for measuring hydrogen peroxide, and
- (C) a glucosone-oxidizing and decomposing enzyme.

Claim 11 (Currently Amended) [:] A method for reducing the effect of a fructosyl lysine compound in an assay of glycated protein contained in a sample, the method comprising: treating the sample with a protease to thereby release fructosyl valine or fructosyl valylhistidine[.,];

and causing reacting a fructosyl peptide oxidase , a reagent for measuring hydrogen peroxide, and or a glucosone-oxidizing and decomposing enzyme with at least the following (A) to (C) to act on the released fructosyl valine or fructosyl valylhistidine at a pH of 4.0 to 7.0 and correlating a product resulting from the action of (A) to (C) to in the presence or absence of a glycated protein in the sample [:

- (A) a fructosyl peptide oxidase,
- (B) a reagent for measuring hydrogen peroxide, and
- (C) a glucosone-oxidizing and decomposing enzyme]].

Claim 12 (Currently Amended) [: A] The method according to of claim 11, wherein the glycated protein is a glycated hemoglobin.

Claim 13 (Currently Amended [: A] The method according to of 11 or 12, wherein the protease is obtained from (A) a microorganism belonging to ~~the~~ a genus selected from the

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group consisting of Bacillus, Aspergillus, ~~or~~ and Streptomyces, or (B) is obtained from a gene of the microorganism of (A) through a gene recombination technology.

Claim 16 (Currently Amended) [[: A]] The method [[according to]] of claim [[s]] 10 or 11, wherein the enzyme for assaying fructosyl valine or fructosyl valylhistidine is a fructosyl peptide oxidase.

4. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled “Comments on Statement of Reasons for Allowance”.

### **Conclusion**

6. Claims 2-4, 7, 9-13 and 16 are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope A. Robinson whose telephone number is 571-272-0957.

The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Robert Mondesi, can be reached at (571) 272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/Hope A. Robinson/

Primary Examiner, Art Unit 1652